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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,379	01/05/2001	Wouter Cornelis Puijk	P51196US00	3527

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EXAMINER	
ALEXANDER, LYLE	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/754,379	PUIJK ET AL.
	Examiner	Art Unit
	Lyle A Alexander	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/5/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite what is structure is intended by "grafted with hydroxymethylmethacrylate" (e.g. what is being grafted ?).

Claim 9 is vague and indefinite what is intended by a "library of peptides".

Specification

The specification teaches hydroxymethylmethacrylate as being abbreviated by "HEMA". Upon searching the art, it was noticed that HEMA is widely recognized as representing hydroxyethylmethacrylate (see Ebersole et al. cited below). Applicants are their own lexicographer and can define HEMA in any means they choose, as in the instant specification. The Office just wants to make sure on the record that hydroxymethylmethacrylate and not hydroxyethylmethacrylate is what Applicants intend for HEMA.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berenson et al.

Berenson et al. teach in example 15 in column 20 lines 14+ placing the samples in flat bottomed microtiter plates. Column 21 lines 17+ teach hydroxymethylmethacrylate is known a solid support material and can be utilized as a surface for the microtiter wells.

Berenson et al. are silent to the claimed volume of the microtiter wells, their depth to diameter ratio and their density on the plate.

The court decided In re Rose (105 USPQ 237) " ... the size of the article under consideration which is not ordinarily a matter of invention...". The Office has read the claimed 0.1-5 microliter volume range as being the size of the article. Further, it is desirable to minimize the size or volume or a microtiter well to gain the advantages of reducing the amount of sample and reagents needed (e.g. minimize the cost of reagents).

It would have been within the skill of the art to modify Berenson et al. and make the microtiter plate well have a volume of 0.1-5 microliters to minimize the amount of sample and reagent required to gain the above advantages and because changes in the size or volume are not ordinarily a matter of invention in view of Rose above.

The court decided In re Dailey (149 USPQ 47) that "... the configuration of the container is a mere matter of choice and not significantly novel over ..." the art of record. The Office has read the claimed density of the well as the configuration of the plate. It is desirable to make the well as densely packed as possible to save on the cost of materials and space required for sample analysis.

It would have been within the skill of the art to modify Berenson et al. and have a well density of 10-15 wells per square centimeter to gain the above advantages and because the configuration of the container is a mere matter of choice in view of Dailey above.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stedronsky.

In light of the 35 USC 112 second paragraph issues above, the Office has read, "grafted" as meaning made of and "library" as meaning being able to make different peptides.

The Office does not have immediate to the earlier application 08/811,959 from which this application is a CIP. The Office is using the 1/5/01 filing date for the subject matter covered by the instant claims. The Office will assume the instant claims contain new subject matter that is not entitled to the earlier filing date before 1/5/01.

Stedronsky teaches in column 5 lines 26+ and specifically line 41 teach the claimed hydroxymethylmethacrylate as a desirable biocompatible plastic material. Further line 45 teaches multiwell plates can be made of this plastic. Further, the balance of this reference teaches PTC derivatization of polymers which has been read on the claimed "library of peptides" where each peptide comprises from 25-35 amino acids. Stedronsky is silent to the claimed volume of the microtiter wells, their depth to diameter ratio and their density on the plate.

The court decided In re Rose (105 USPQ 237) " ... the size of the article under consideration which is not ordinarily a matter of invention...". The Office has read the claimed 0.1-5 microliter volume range as being the size of the article. Further, it is desirable to minimize the size or volume or a microtiter well to gain the advantages of reducing the amount of sample and reagents needed (e.g. minimize the cost of reagents).

It would have been within the skill of the art to modify Stedronsky and make the microtiter plate well have a volume of 0.1-5 microliters to minimize the amount of sample and reagent required to gain the above advantages and because changes in the size or volume are not ordinarily a matter of invention in view of Rose above.

The court decided In re Dailey (149 USPQ 47) that "... the configuration of the container is a mere matter of choice and not significantly novel over ..." the art of record. The Office has read the claimed density of the well as the configuration of the plate. It is desirable to make the well as densely packed as possible to save on the cost of materials and space required for sample analysis.

It would have been within the skill of the art to modify Stedronsky and have a well density of 10-15 wells per square centimeter to gain the above advantages and because the configuration of the container is a mere matter of choice in view of Dailey above.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lam et al.

Lam et al. teach a multiwell test device comprising a library of peptides including peptides having at least 18 amino acids and from 25 to 35 amino acids linked to non-peptide second segments. Lam et al. are silent to the claimed volume of the microtiter wells.

The court decided In re Rose (105 USPQ 237) " ... the size of the article under consideration which is not ordinarily a matter of invention...". The Office has read the claimed 0.1-20 microliter volume range as being the size of the

article. Further, it is desirable to minimize the size or volume or a microtiter well to gain the advantages of reducing the amount of sample and reagents needed (e.g. minimize the cost of reagents).

It would have been within the skill of the art to modify Lam et al. and make the microtiter plate well have a volume of 0.1-20 microliters to minimize the amount of sample and reagent required to gain the above advantages and because changes in the size or volume are not ordinarily a matter of invention in view of Rose above.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ebersole et al. characterize in column 9 lines 29-30 hydroxyethylmethacrylate as HEMA.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander
Primary Examiner
Art Unit 1743

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